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Louis B. Jacques, MD
Director, Division of Items and Devices
Centers for Medicare and Medical Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
7500 Security Blvd.
Mail Stop C1-09-06
Baltimore, MD 21244

Re: Formal Request for Reconsideration of the National Coverage Determination (NCD) for Magnetic Resonance Imaging (MRI) to revise the Contraindication for Cardiac Pacemakers (Sections 220.2 of the Medicare NCD Manual; other diagnostic tests §1861(s)(3))

Dear Dr. Jacques:

I am writing to formally request a revision of the current policy regarding coverage of clinically-indicated magnetic resonance imaging (MRI) for patients with permanent pacemakers and implantable cardioverter-defibrillators (ICD). As you are aware, it is stated in the current Medicare National Coverage Determinations Manual that payment for an MRI examination is not covered for patients with cardiac pacemakers although ICDs are not specifically mentioned (section 220.2, section C.1.).

We would like to request that the current Medicare National Coverage Determination language be modified to provide an exception for patients with cardiac devices who undergo MRI when: (1) a clinically-indicated MRI is performed as part of a prospective clinical trial designed to determine the risk of the procedure, and (2) the study is conducted after an Investigational Device Exemption (IDE) has been approved by the Food and Drug Administration (FDA) for the proposed research.

The number of patients in the United States with permanent pacemakers and ICDs is increasing rapidly, with more than 2.8 million pacemakers and 690,000 ICDs placed between 1990 and 2005.[1-3] During the same period, MRI has become the imaging modality of choice for the evaluation of many diseases of the brain, spinal cord, and musculoskeletal system. It is estimated that a patient with a permanent pacemaker or ICD will have a 50-75% chance of requiring an MRI during the lifetime of the implanted device.[4]

The presence of a pacemaker or ICD is considered to be a contraindication to MRI.[5-8] As a result, many patients with cardiac devices have been denied access to MRI, although it may be the most appropriate diagnostic imaging modality. A strategy for mitigating risks for patients with legacy devices and leads who undergo MRI will remain an enduring problem despite the development of "MRI-conditional" cardiac devices. For these patients, it is important to establish the frequency of device-related events in patients undergoing MRI so that treating physicians may conduct informed conversations with their patients regarding the risk of the scan when no acceptable alternative imaging modality is available.

Recent studies have suggested that MRI can be performed with minimal risk for patients who have pacemakers or ICDs as long as the patients are properly monitored and the device is appropriately reprogrammed pre- and post-scan.[5-21] However, to accurately determine the risk of MRI for patients with implanted cardiac devices, additional large-scale, prospective studies are needed.

Improved access to MRI for patients (Medicare beneficiaries) with pacemakers and ICDs will improve health outcomes. For example, MRI has been proven to be superior to computed tomography (CT) for the evaluation of acute intracerebral hemorrhage, and acute ischemic stroke, and for the detection of multiple sclerosis lesions.[22-24] In addition, Appropriateness Criteria from the American College of Radiology rates MRI higher than CT for clinical decision-making in patients with acute and progressive myelopathy, brain metastases, acute and progressive ataxia, and suspected soft tissue masses.[25-28] Therefore, the use of CT rather than MRI for pacemaker and ICD patients may lead to an incorrect diagnosis and ultimately inappropriate or incomplete therapy in many disease states.

Therefore, we respectfully request the language in section 220.2, section C.1; other diagnostic tests §1861(s)(3). in the National Coverage Determination be revised to read as follows: "The MRI is not covered when the following patient-specific contraindications are present. It is not covered for patients with cardiac pacemakers, or with metallic clips on vascular aneurysms. ***However, a clinically-indicated MRI procedure is covered for patients with pacemakers or ICDs if the patient is enrolled in a prospective clinical trial designed to determine the risk of the MRI procedure. Such a trial should be conducted after an Investigational Device Exemption (IDE) has been obtained from the FDA."***

Thank you for your consideration. If you have any questions or require additional information, please feel free to contact me at 858-554-8858 or by email at Russo.Robert@scrippshealth.org.

Sincerely,

Robert J. Russo, MD, PhD
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Attachment (Bibliography)

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